REMARKS

By way of summary, Claims 1 and 3-49 were pending in this application. Of these, Claims 3, 13-26, 31-37, 42, 46, and 49 have been withdrawn. Claims 1, 38, 44, are amended herein. New Claims 50 and 51 are added herein. Accordingly, Claims 1, 4-12, 27-30, 38-41, 43-45, 47, 48, and 50-51 remain pending for consideration.

Rejection of Claims 1, 4-8, 11, 12, 27-30, 38-41, 43-45, and 48 Under 35 U.S.C. § 102(b)

The Examiner rejects Claims 1, 4-8, 11, 12, 27-30, 38-41, 43-45, and 48 under 35 U.S.C. § 102(b) as being unpatentable over at least one of U.S. Patent No. 5,785,686 to Runge, U.S. Patent No. 4,540,402 to Aigner, U.S. Patent No. 4,134,402 to Mahurkar, and U.S. Patent No. 5,618,267 to Palestrant. Applicants disagree with the Examiner's characterization of these references. However, to expedite allowance of this application, Applicants have amended the claims to more clearly distinguish over these references. Applicants reserve the right to pursue broader claims at a later date.

Runge

Runge is directed to a biventricular total cardiac support system that is applied by thoracic invasion, through walls of a heart and lacks the claimed proximal apertures for perfusion. See Figure 1 and Column 4, lines 35-40.

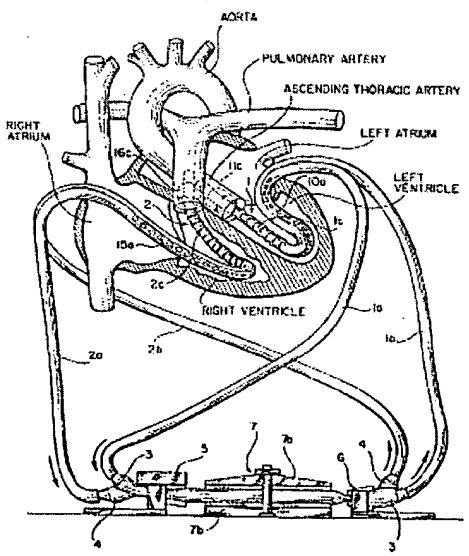

FIG. 1

Cannulae 1 and 2 of the Runge system communicate with the left ventricle and ascending thoracic aorta, and the right ventricle and pulmonary artery. The cannula 1 includes a tube 1a,

which is connected to the inlet of a compressible conduit 3, and a tube 1b, which is connected to the outlet of the compressible conduit 3. See Figure 1. The cannula 2 is similarly connected with a compressible conduit 4. See Figure 1. The diverging tubes 1a, 1b of the cannula 1 present *a high-profile proximal end* that is not configured for application through a single cannulation site. To the contrary, from Figure 1 it appears that substantial invasion of the thorax is required to apply the cannulae 1 and 2 directly to the heart.

Moreover, Runge expressly teaches away from application of the system of Figure 1 through a vessel wall. For example, Runge notes that insertion of the system through a vessel wall would be disadvantageous because of the potential of generating emobli. Column 4, lines 49-52. The only communication between the Runge system and a vessel portion is achieved through a valve not through a cannulation site. Thus, Runge expressly teaches away from modifying the Runge system of Figure 1 for application to a vessel of a patient by way of a single cannulation site.

Furthermore, the Runge system lacks the claimed proximal apertures for maintaining or enhancing perfusion of blood to the patient's vasculature downstream of where the aperture resides in the vasculature. A plurality of aspiration orifices 10a that communicate with a lumen 10 of the cannula 1 are provided in a side wall of a tube 8 of the cannula 1. When applied, the cannula 1 is directed through a wall of the heart and through a heart valve into the ascending thoracic aorta such that the aspiration orifices 10a are positioned in the left atrium and left ventricle. The orifices 10a of the cannula 1 do not aid in perfusion but rather they *drain the left atrium and ventricle to decompress the heart.* See Column 3, line 67-Column 4, line 4. The cannula 2 is similarly placed in the system by guiding the distal end thereof through a wall of the heart and into the pulmonary artery and positioning aspiration orifices 15a in the right atrium and right ventricle. Like the orifices 10a, the orifices 15a do not aid in perfusion but rather they *drain the right atrium and ventricle.* See Column 4, lines 17-21.

In contrast, Claim 1 recites, among other things, a multilumen catheter comprising:

> a catheter body having *a proximal end configured to enable the catheter to be applied through a single cannulation site,* a first distal end, and a second distal end, said first distal end extending distally further from the proximal end than the second distal end;

a first lumen extending between said first distal end and said proximal end;

a second lumen extending between said second distal end and said proximal end; and

at least one aperture in one of said lumens positioned near the proximal end *so that the aperture may maintain or enhance perfusion of blood to the patient's vasculature downstream of where the aperture resides in said vasculature* when said catheter is inserted into the patient for treatment.

Runge does not teach or suggest all of the limitations of Claim 1 set forth above. Therefore, Applicants respectfully submit that Claim 1 is patentably distinguished over Runge. Applicants note that the Office Action states that Claim 2 is also rejected in view of Runge. The rejection of Claim 2 will not be addressed because this claim was canceled in the Response filed March 24, 2003. Claims 4, 6-8, and 12 depend from Claim 1 and further define the invention thereof. Therefore, Claims 4, 6-8, and 12 are allowable at least for the same reasons that Claim 1 is allowable. Applicants respectfully request allowance of Claims 1, 4, 6-8, and 12 over Runge.

Similarly, Claim 27 recites, among other things, an extracardiac pumping system for supplementing blood circulation in a patient *without any component thereof being connected to the patient's heart*, the extracardiac system comprising:

a pump configured to pump blood through the patient *at subcardiac flow rates*, said pump having an average flow rate that, during normal operation thereof, is substantially below that of the patient's heart when healthy;

an inflow conduit fluidly coupled to the pump to direct blood to the pump from a first blood vessel;

an outflow conduit fluidly coupled to the pump to direct blood from the pump to a second blood vessel; and

a multilumen catheter for directing the flow of blood through a patient through a single cannulation site, said catheter comprising

a catheter body having a proximal end, a first distal end, and a second distal end, said first distal end extending distally further from the proximal end than the second distal end;

a first lumen extending between said first distal end and said proximal end, said first lumen in fluid communication with one of said conduits; and

a second lumen extending between said second distal end and said proximal end, said second lumen in fluid communication with one of said conduits.

Runge does not teach or suggest all of the limitations of Claim 27 set forth above. Therefore, Applicants respectfully submit that Claim 27 is patentably distinguished over Runge. Claims 28-30 depend from Claim 27 and further define the invention thereof. Therefore, Claims 28-30 are allowable at least for the same reasons that Claim 27 is allowable. Applicants respectfully request the allowance of Claims 27-30 over Runge.

Similarly, Claim 38 recites, among other things, a multilumen catheter *for directing the flow of blood through a patient through a single cannulation site* comprising:

a catheter body having *a proximal end configured to enable the catheter to be applied through a single cannulation site*, a first distal end, a second distal end, a first lumen extending between said first distal end and said proximal end, and a second lumen extending between said second distal end and said proximal end;

said first distal end extending further from the proximal end than the second distal end; and

a means for *maintaining or enhancing perfusion to the patient's vasculature downstream of a point of entry of said catheter into a blood vessel* when said catheter is inserted into the patient for treatment.

Runge does not teach or suggest all of the limitations of Claim 38 set forth above. Therefore, Applicants respectfully submit that Claim 38 is patentably distinguished over Runge. Claims 39-41 and 43 depend from Claim 38 and further define the invention thereof. Therefore, Claims 39-41 and 43 are allowable at least for the same reasons that Claim 38 is allowable. Applicants respectfully request the allowance of Claims 38-41 and 43 over Runge.

Similarly, Claim 44 recites, among other things, a multilumen catheter for directing the flow of blood through a patient *through a single cannulation site* comprising:

a catheter body having *a proximal end configured to enable the catheter to be applied through a single cannulation site*, a first distal end, a second distal end,

a first lumen extending between said first distal end and said proximal end, and a second lumen extending between said second distal end and said proximal end, said first distal end extending further from the proximal end than the second distal end;

a tip located at the first distal end of the catheter for directing blood from the first lumen into the vasculature;

means for connecting a first conduit to said first lumen and for connecting a second conduit to said second lumen; and

means for maintaining or enhancing perfusion to the patient's vasculature downstream of a point of entry of said catheter into a blood vessel when said catheter is inserted into the patient for treatment.

Runge does not teach or suggest all of the limitations of Claim 44 set forth above. Therefore, Applicants respectfully submit that Claim 44 is patentably distinguished over Runge. Claims 45 and 48 depend from Claim 44 and further define the invention thereof. Therefore, Claims 45 and 48 are allowable at least for the same reasons that Claim 44 is allowable. Applicants respectfully request the allowance of Claims 44, 45, and 48 over Runge.

Aigner

Applicants note with thanks the Examiner's consideration of Applicants' arguments in connection with the Aigner reference set forth in the Response filed March 24, 2003. In the Office Action, the Examiner acknowledges an important distinction between the structures disclosed in Aigner and the preferred embodiment of this application, namely the Aigner catheter has a trifurcated proximal end. Applicants note that, like Runge, discussed above, this and other aspects of the arrangement disclosed in Aigner preclude application of such arrangement by way of a minimally invasive procedure, e.g., through a single cannulation site.

In particular, as previously discussed, Aigner discloses a branched catheter that has three distinct proximal ports, i.e., the Aigner catheter is trifurcated. See Figure 1, reproduced below. Aigner discloses an arrangement that includes a splint catheter 1 and a second catheter tube 3 mounted to the splint catheter 1. The splint catheter 1 and the second catheter tube 3 form first and second proximal ports. A shunt tube 2 is attached to the splint catheter 1 at a location off-set from the second catheter tube 3 and forms a third proximal port. Column 2, lines 6-8.

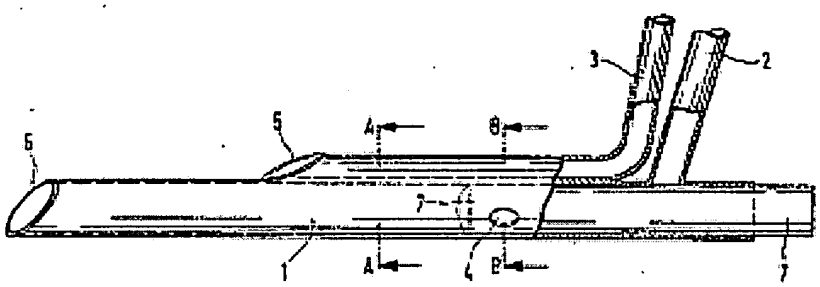

Figure 1

In addition to the expansive profile of the trifurcated proximal end of the Aigner catheter, a *solid rod* 7 is inserted into the back end of the splint catheter 1 to temporarily close a lateral opening 4 in the splint catheter 1. Column 2, lines 22-25. When nearly fully withdrawn from the proximal port of the splint catheter 1, the profile of the proximal end of the Aigner catheter is even greater.

In contrast to the present invention, major surgery is required to implant the Aigner catheter. As discussed above and previously, the Aigner catheter is branched with three distinct proximal ports. In addition, the Aigner catheter requires manipulation of a solid rod 7 inserted into the proximal port of the splint catheter 1 after implantation. This arrangement would *require an extremely long incision* of the vena cava to permit the withdrawal of the rod 7. Furthermore, in application, the splint catheter 1 is placed in and ligated to the vena cava, i.e., the vessel is cinched onto the splint catheter 1 from the vessel's outer surface. Column 4, lines 42-45. This ligation would presumably require open surgical access to the thorax, where the distal end of the Aigner catheter resides when applied.

In addition, Claim 1, as amended herein, recites a multilumen catheter comprising:

> *a catheter body having a proximal end configured to enable the catheter to be applied through a single cannulation site, a first distal end, and a second distal end, said first distal end extending distally further from the proximal end than the second distal end;*
>
> a first lumen extending between said first distal end and said proximal end;

a second lumen extending between said second distal end and said proximal end; and

at least one aperture in one of said lumens positioned on the catheter body such that the apertures is closer to the cannulation site than to the first or the second distal ends when said catheter is inserted into the patient so that the aperture may maintain or enhance perfusion of blood to the patient's vasculature downstream of where the aperture resides in said vasculature when said catheter is inserted into the patient for treatment.

Aigner does not teach or suggest all of the limitations of Claim 1 set forth above. Therefore, Applicants respectfully submit that Claim 1 is patentably distinguished over Aigner. As noted above, the rejection of Claim 2 in view of Aigner set forth in the Office Action will not be address as this claim was previously canceled.

Mahurkar

Like Runge and Aigner, Mahurkar does not teach or suggest all of the limitations of amended Claim 1. Mahurkar is directed to a double lumen hemodialysis catheter. Mahurkar discloses a catheter 1 having lumens 2 and 3 and an aperture 32 *near the tip* of lumen 2. See Figure 1 and Column 2, lines 45-48. The distal tip aperture 32 enables continued flow *into the catheter* 1 when an opening defined at a beveled edge 4 becomes obstructed.

Applicants do not agree with the Examiner's construction of "near the proximal end," i.e., that it is broad enough to include the structure disclosed in Mahurkar, which is an aperture "near the tip" of the lumen 2. Applicants refer the Examiner to M.P.E.P. § 2173.05(b), which states that relative terminology is acceptable if one of ordinary skill in the art "would be reasonably appraised of the scope of the invention." Here, one skilled in the art would be reasonably appraised of the scope of the invention based on the use of the term "near the proximal end." For example, the claim itself helps clarify what is meant by "near the proximal end." Claim 1 recites, in part, a multilumen catheter comprising:

> at least one aperture in one of said lumens positioned near the proximal end *so that the aperture may maintain or enhance perfusion of blood to the patient's vasculature downstream* of where the aperture resides in said vasculature when said catheter is inserted into the patient for treatment.

One skilled in the art would recognize from Claim 1 that the aperture must be capable of maintaining or enhancing perfusion downstream of where the catheter is inserted into the patient's vasculature. This capability is further illustrated in one embodiment with reference to Figure 6, wherein the apertures 28 of the multilumen catheter 10 are shown maintaining or enhancing the blood flow to downstream tissue when the catheter is inserted into the patient.

Applicants respectfully submit that Claim 1 is patentably distinguished over Mahurkar because all of the limitations of Claim 1 are not taught or suggested by Mahurkar. Claims 5, 6, and 8, which also are rejected under 35 U.S.C. § 102(b) in view of Mahurkar, depend from Claim 1 and further define the invention thereof. Therefore, these claims are patentably distinguish over Marhurkar at least for the same reasons that Claim 1 is distinguished thereover. Applicants respectfully request the allowance of Claims 1, 5, 6, and 8 over Mahurkar.

Palestrant

Like Runge, Aigner, and Mahurkar, Palestrant does not teach or suggest all of the limitations of amended Claim 1. Palestrant is directed to a method for establishing a collapsible infusion conduit. Figure 11 illustrates an embodiment of a catheter having more than one lumen. The catheter of Figure 11 is formed of a first elongated, generally flattened strip 32 of flexible material having first and second opposing sides 34 and 36. The first strip 32 extends the length of catheter 20 from trailing end 24 to leading end 22. The catheter also includes a second elongated, generally flattened strip 38 of flexible material having first and second opposing sides 40 and 42 that extends the length of catheter 20 from trailing end 24 to leading end 22. A third elongated, generally flattened strip 84 of the same flexible material as strips 32 and 38 is secured along its side edges with the respective side edges of first strip 32 to form a second elongated, normally-flattened tube in parallel with tube 44. The collapsed lumen of the second tube is designated by reference numeral 86. The third strip 84 may be made shorter in length than strips 32 and 38 to create a shorter second lumen 86 having an exit port that is longitudinally displaced from the exit port of the first lumen. Palestrant does not disclose any of the strips 32, 38, and 84 having apertures in fluid communication with either of the lumens defined thereby, let alone any proximal apertures that may maintain or enhance perfusion.

In contrast, as set forth above, Claim 1 recites, among other limitations, "a multilumen catheter comprising . . . at least one aperture in one of said lumens positioned near the proximal end . . . ." Therefore, Applicants respectfully submit that Claim 1 is patentably distinguished

over Palestrant. Claims 11 and 12 are also rejected under 35 U.S.C. § 102(b) in view of Palestrant. These claims depend from Claim 1 and further define the invention thereof. Therefore, Claims 11 and 12 are patentably distinguished over Palestrant at least for the same reasons that Claim 1 is patentable thereover. Applicants respectfully request the allowance of Claims 1, 11, and 12 over Palestrant.

Rejection of Claims 5, 9-11, and 47 Under 35 U.S.C. § 103(a)

The Examiner rejects Claims 5, 9-11, and 47 under 35 U.S.C. § 103(a) as being unpatentable over Runge alone. The Examiner asserts that Runge arguably shows a tapered tip and the Examiner suggests that the claims should be limited to a preformed bend. The Examiner further asserts that the subject matter of these claims would have been obvious to one of skill in the art.

Applicants respectfully traverse these rejections because, as discussed above, Runge, even if modified as the Examiner suggests, fails to teach or suggest the elements of Claim 1 from which Claims 5 and 9-11 depend and Claim 44 from which Claim 47 depends. See M.P.E.P. § 2143 (stating that in order to establish a *prima facie* case of obviousness for a claim, the prior art references must teach or suggest all the claim limitations). Accordingly, Applicants respectfully submit that for at least these reasons, Claims 5, 9-11, and 47 are patentably distinguished over Runge, and Applicants respectfully request allowance of Claims 5, 9-11, and 47.

CONCLUSION

For the foregoing reasons, Applicants respectfully assert that the present application is in condition for allowance, and Applicants respectfully request that a Notice of Allowance be issued at the earliest opportunity.

Respectfully submitted,

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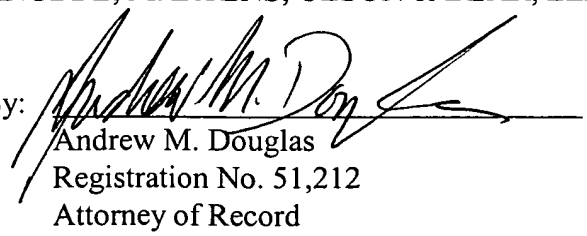
Dated: December 18, 2003

By: 

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